

b.) Remarks

Claim 72 has been amended in order to correct a typographical error.

Accordingly, no new matter has been added.

Claims 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In support of the rejection, the Examiner states that

Experiments 3 and 4 as pointed out by the applicant show tablet compressed at pressure of 1000 kg/punch (less than 1.3 ton) lost sustained release function and enteric function, respectively (see page 66, 4th paragraph through page 68, 1st paragraph). (Office Action, page 3, lines 4-7.)

As shown in Experiment 1 at specification pages 46 to 47, tableting is executed with a die and punch having 7mm diameter (3.5 mm radius). Namely, for tableting with a die and punch of $0.35 \times 0.35 \times \pi^1$ (cm²), with a punch operated at 1000 kg/punch corresponds to $1000 (0.35 \times 0.35 \times \pi)$ (kg/cm²) = 2.6 (ton/cm²).

However, in Experiments 3 and 4 at specification pages 66 to 68 noted by the Examiner, the punch is operated at 500 kg/punch, so the tableting pressure is therefore 1.3 (ton/cm²).

As seen from the dissolution test in Tables 4 and 5, it is clear that (1) Experiments 3 and 4 provided tablets obtained with a tableting pressure of 1.3 (ton/cm²), (2) such tablets did not lose sustained release function or enteric function, and (3) tablets

¹ Area = πr^2

obtained by Comparisons 7 and 8 (in which the tableting pressure is 2.6 ton/cm^2) lost both sustained release function and enteric function.²

Claims 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 are rejected under 35 U.S.C. §112, first paragraph, as failing to enable one of ordinary skill. In support of this rejection, the Examiner states

the specification fails to describe how to precisely achieve the claimed tableting pressure greater than 1 ton/cm^2 (up to 1.3 ton/cm^2). (Office Action, page 4, lines 7-9).

Respectfully submitted, this is trivial as explained above. As is plainly very well-known to those of ordinary skill, tableting pressure is simply a function of punch pressure and the surface area of the punch and die surfaces, and can thus readily be manipulated as desired. Moreover, although the Examiner states

Further, contrary to the claims, the working examples show that the properties of the tablet (e.g., sustained function and enteric function) are destroyed at tableting pressure of 1000 kg/punch (1 ton) (see pages 66-68). As a matter of facts, experiments 3 and 4 show that the produced tablet that can maintain the functions of a compressed tablet is at a tableting pressure of 500 kg/punch , which is 0.5 ton . This tableting pressure is outside of the range recited in the claims, namely, from 0.7 - 1.3 ton . Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to make and/or use the claimed method to prepare tablet with adequate hardness, and maintaining a function of a compressed tablet at tableting pressure recited in the claims. (Office Action, page 4, lines 10-19).

² In specification pages 50 to 51, the hardness and dissolution time of tablets produced at 0.7 ton/cm^2 are compared between the experiment 1 of the production method of the present invention and the comparisons 1 and 2. The results evidence that tablets produced at the tableting pressure of 0.7 ton/cm^2 according to the production method of experiment 1 have a practical hardness and their dissolution time is both short and consistent.

To the extent this rejection is maintained, Applicants have above illustrated the error in the Examiner's technical analyses of tableting pressure and the excellent results evidenced by the present invention.

Claims 42, 46, 53, 63, 73, 80, 84, 91 and 99-102 are rejected under 35 U.S.C. §103(a) as being unpatentable over Roche (U.S. Patent No. 5,075,114), in view of Rotman (U.S. Patent No. 4,710,384). Claims 43, 72 and 81 are rejected under 35 U.S.C. §103(a) as being unpatentable over Roche, in view of Rotman and Morimoto (EP 0 650 826).

The Examiner's bases of rejection are set forth from pages 5-7 of the Office Action.

This rejection is respectfully traversed. Prior to setting forth their bases for traversal, however, Applicants would briefly like to discuss the salient features of the present invention and *inter alia* its patentable nature over the prior art.

As the Examiner is well-aware, the present invention proposes a production method of tablet including "granule containing coating film and an active substance which is destroyed when being compressed at tableting pressure greater than 1.3 (ton/cm²)" or "granule containing base matrix or an active substance which is destroyed when being compressed at tableting pressure greater than 1.3 (ton/cm²)". It is characterized in that (1) lubricant is applied only to the die and punches (2) so as to provide lubricant only on the surface of the tablet and (3) that material is compressed at tableting pressure of 0.7 to 1.3 (ton/cm²).

The production method of the present invention having such characteristics can achieve the effect that breakage of granule by tableting is prevented and further a tablet with required hardness and very small variation of dissolution time can be produced.

Neither these features, nor these advantages, are taught or suggested by the prior art.

As suggested by the Examiner, Rotman discloses the microcapsule is destroyed at tableting pressure of 1.5 ton/punch. Rotman describes that the microcapsule is coated in order to “produce a tablet without breaking the microcapsule”. Namely, Rotman does not disclose that “granule containing coating film and an active substance which is destroyed when being compressed at tableting pressure greater than 1.3 (ton/cm²)” and “granule containing base matrix and an active substance which is destroyed when being compressed at tableting pressure greater than 1.3 (ton/cm²)”.

Accordingly, Rotman discloses a coated microcapsule which is not broken 1.5 (ton/punch) as a tablet component but does not teach or suggest granules and does not teach or suggest tableting pressures 0.7 to 1.3 ton/cm². These deficiencies are not addressed by any of the other cited references.

Moreover, in any event, the prior art does not respond to Applicants’ conclusive showing that tablets produced according to the present invention are 25% harder than those of the prior art. At least for this reason, any *prima facie* obviousness is rebutted and the nonobviousness of the pending claims is established, as discussed in Applicants’ November 7, 2008 Preliminary Amendment.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Lawrence S. Perry/
Lawrence S. Perry
Attorney for Applicants
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

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